# PATENT COOPERATION TRLATY

	From the INTERNATIONAL BUREAU
PCT	То:
NOTIFICATION OF ELECTION  (PCT Rule 61.2)  Date of mailing (day/month/year) 19 March 2001 (19.03.01)	Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No.	Applicant's or agent's file reference
PCT/US00/18051	235.00310201
International filing date (day/month/year)	Priority date (day/month/year)
30 June 2000 (30.06.00)	01 July 1999 (01.07.99)
Applicant	
FAYRER-HOSKEN, Richard et al	
in a notice effecting later election filed with the Inte	2001 (31.01.01)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer S. Mafla

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

**PCT** 



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant'	's or ag	ent's file reference		N 46			
235.003	_		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)			
Internation	nal app	lication No.	International filing date (day/mo	nth/year)	Priority date (day/month/year)		
PCT/US	500/18	3051	30/06/2000		01/07/1999		
Internation A61K39		ent Classification (IPC) or n	national classification and IPC	· · · · · · · · · · · · · · · · · · ·			
Applicant							
THE UN	IIVER	SITY OF GEORGIA F	RESEARCH FOUNDATION,	INC			
1. This and i	1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.						
2. This	REPO	RT consists of a total of	f 7 sheets, including this cover	sheet.			
(	This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of sheets.						
3. This r	report	contains indications rela	ating to the following items:				
1	_	Basis of the report					
II 		Priority					
III IV			ppinion with regard to novelty, in	ventive step a	and industrial applicability		
V	$\boxtimes$	Lack of unity of invention Reasoned statement uncitations and explanations		novelty, inver	ntive step or industrial applicability;		
VI		Certain documents cite					
VII		Certain defects in the ir					
VIII			n the international application				
Date of subi	mission	of the demand	Date of	completion of th	nis report		
31/01/200	01		01.10.2	001			
		address of the international ng authority:	Authoriz	ed officer	ST ISOUS MIZUL		
	D-802	ean Patent Office 98 Munich 19 89 2399 - 0 Tx: 523656	Herrer	o, M	Lineal Sales		
Fax: +49 89 2399 - 4465				ne No. +49 89 2	2399 8542		

International application No. PCT/US00/18051

I.	Ва	sis of the report				
1	1. With regard to the lements of the international application (Replacement sheets which have been furnished the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)): Description, pages:					
	1-1	8 as originally filed				
	Cla	aims, No.:				
	1-2	as originally filed				
2.	Wit lang	h regard to the <b>language</b> , all the elements marked above were available or furnished to this Authority in the guage in which the international application was filed, unless otherwise indicated under this item.				
	These elements were available or furnished to this Authority in the following language: , which is:					
		the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).				
		the language of publication of the international application (under Rule 48.3(b)).				
		the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).				
3.	With	n regard to any <b>nucleotide and/or amino acid sequence</b> disclosed in the international application, the rnational preliminary examination was carried out on the basis of the sequence listing:				
		contained in the international application in written form.				
		filed together with the international application in computer readable form.				
		furnished subsequently to this Authority in written form.				
		furnished subsequently to this Authority in computer readable form.				
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.				
		The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.				

5. 
This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

☐ the description,

☐ the claims,

☐ the drawings,

4. The amendments have resulted in the cancellation of:

pages:

Nos.:

sheets:

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

		, op or u,				
6	. Ad	ditional observations, if	necess	ary:		
11	l. No	n-establishment of op	inion w	ith regar	rd to novelty, inventive step and industrial applicability	
1.	. The	e questions whether the vious), or to be industria	claime Ily appli	d inventio icable hav	on appears to be novel, to involve an inventive step (to be nonve not been examined in respect of:	
		the entire international	applica	ation.		
	×	claims Nos. 17-26 with	respec	ct to indus	strial applicability.	
be	ecau	se:				
	×	the said international a does not require an int see separate sheet	ipplicati ernatioi	on, or the nal prelim	e said claims Nos. 17-26 relate to the following subject matter which in any examination (specify):	:h
		the description, claims that no meaningful opi	or draw	vings ( <i>ind</i> uld be forr	dicate particular elements below) or said claims Nos. are so unclearmed (specify):	ar
	□	the claims, or said clair could be formed.	ms Nos	. are so i	inadequately supported by the description that no meaningful opin	ior
		no international search	report	has been	n established for the said claims Nos	
2.	and	eaningful international p or amino acid sequence ructions:	orelimina e listing	ary exami to comply	nination cannot be carried out due to the failure of the nucleotide ly with the standard provided for in Annex C of the Administrative	
		the written form has no	t been f	urnished	or does not comply with the standard.	
					en furnished or does not comply with the standard.	
V.	Rea citat	soned statement unde tions and explanations	er Articl s suppo	le 35(2) w orting suc	with regard to novelty, inventive step or industrial applicability ch statement	<b>;</b>
1.	State	ement				
	Nov	elty (N)	Yes: No:	Claims Claims		
	Inve	ntive step (IS)	Yes: No:	Claims Claims		
	Indu	strial applicability (IA)	Yes:	Claims	1-16, 27, 28	

International application No. PCT/US00/18051

No: Claims

2. Citations and explanations see separate sheet

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted: see separate sheet

# VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made: see separate sheet

## **SECTION III**

Claims 17-26 relate to medical uses considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

## **SECTION V**

- 2. CITATIONS AND EXPLANATIONS
- 2.1 The following document has been considered for the purposes of this report:
  - D1: Waclawek, M. et al (1998) Biology of Reproduction **59**:1230-1239 (also cited in the application)
- 2.2 <u>Inventive step</u> (Art. 33(3) PCT)

The present application does not satisfy the criterion set forth in Art. 33(3) PCT because the subject-matter claimed does not involve an inventive step (Rule 65(1)(2) PCT)

No experimental support can be found elsewhere in the description as originally filed showing that the expected technical effects (i.e. immunocontraception or immunosterilization) are obtained.

The technical information provided in Examples I, II and III does not go beyond the teachings of D1. In this regard see that present page 14, lines 25-27 states that in order to isolate avian zona pellucida proteins for the purposes of the alleged invention (Example I) the procedure for isolating perivitelline membranes (pvm) from laid eggs reported in D1 can also be used. It is noted that in addition to the isolation of pvm and characterization of chZPC (chicken homologue of zona pellucida protein-3) D1 discloses the administration (three series of intradermal injections) of purified chZPC in combination with an adjuvant (Freund's complete

or incomplete adjuvant) to rabbits, whereby rabbit anti-chZPC antibodies were raised which could be recovered from the blood (immune sera) of the immunized animals (cf D1, page 1231, left column, 5th paragraph).

In spite of the fact that present Example III refers to "Immunosterilization of dogs using aZP vaccine" the information of relevance derivable from the experimental data therein provided is essentially the same as already known from D1, namely that avian ZP proteins are immunogenic in mammals (see above).

Moreover, although present Example IV refers to "Administration of mixed chicken/porcine ZP vaccine to Psitaccines" the experimental data therein provided do not substantiate that the expected technical results are obtained. First of all, in the light of the language employed (present tense, as in Example III) the possibility cannot be ruled out that Examples III and IV are merely of a predictive nature. Furthermore, with reference to the passage on page 17, lines 25-27, it is not evident that a reduction in egg production would provide a direct evidence of fertility impairment (at least of immunocontraception), since virgin hens are seemingly also capable of laying eggs (cf D1, page 1236, left column, lines 6-9).

Consequently, the application fails to contain the necessary technical information on the basis of which it could be possible to assess whether the various aspects of the invention as defined either in Claims 1-16 and 27-28 (fertility impairing vaccines) or Claims 17-26 (methods for impairing the fertility of an animal) involve an inventive step, contrary to the requirements of Art. 33(3) PCT.

## **SECTION VII**

- The expression "hereby incorporated by reference" in respect of prior art 1. documents on page 17, lines 29-30 leads to a doubt as to whether the requirements of the description being self-contained are satisfied (see PCT Guidelines C-II, 4-17).
- The term "Tween" (pages 10, 15, 16 and 17) appears to be a registered trade 2. mark, but has not been acknowledged as such.

# **SECTION VIII**

- In the light of the supporting description on page 6, lines 30-31 it appears that, 1. instead of its present wording, Claim 12 was intended to read, e.g. "... wherein the polynucleotide is supplied as part of a vector" (Art. 6 PCT)
- The statement in the description on page 17, lines 30-32 bridging over page 18 2. implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

From the

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SANDBERG, Victoria A. Mueting, Raasch, Gebhardt P.O. Box 581415 Minneapolis, MN 55458-1415

ETATS-UNIS D'AMERIQUE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing

(day/month/year)

01.10.2001

Applicant's or agent's file reference

International application No.

235.00310201

International filing date (day/month/year)

Priority date (day/month/year)

IMPORTANT NOTIFICATION

01/07/1999

Applicant

PCT/US00/18051

THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC

30/06/2000

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

RECEIVED

OCT 0 8 2001

Name and mailing address of the IPEA/

Authorized officer

**MUETING & RAASCH** 

D. Te

European Patent Office D-80298 Munich

Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Digiusto, M

Tel.+49 89 2399-8162



# **PATENT COOPERATION TREATY**

# **PCT**

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant'	s or ag	ent's file reference				
235.003	_		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)		
Internation	nal app	lication No.	International filing date (day/month	h/year) Priority date (day/month/year)		
PCT/US	PCT/US00/18051 30/06/2000			01/07/1999		
A61K39		ent Classification (IPC) or na	tional classification and IPC			
Applicant THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC						
1. This and i	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.					
2. This	REPO	ORT consists of a total of	7 sheets, including this cover sh	heet.		
l l	peen a	amended and are the bas	d by ANNEXES, i.e. sheets of the is for this report and/or sheets of 7 of the Administrative Instruction	ne description, claims and/or drawings which have containing rectifications made before this Authority ions under the PCT).		
Thes	e ann	exes consist of a total of	sheets.			
3. This	report	contains indications relat	ting to the following items:			
1	$\boxtimes$	Basis of the report	·			
II						
Ш	$\boxtimes$	Non-establishment of op	oinion with regard to novelty, inve	entive step and industrial applicability		
IV		Lack of unity of invention		•		
٧	Ø	Reasoned statement un citations and explanation	der Article 35(2) with regard to n ns suporting such statement	novelty, inventive step or industrial applicability;		
VI		Certain documents cite	d			
VII	×	Certain defects in the in	ternational application			
VIII	VIII 🗵 Certain observations on the international application					
Date of sub	missio	n of the demand	Date of co	completion of this report		
31/01/20	01		01.10.200	001		
	exami	address of the international ning authority:	Authorize	ed officer		
<u></u>	D-80	pean Patent Office 298 Munich +49 89 2399 - 0 Tx: 523656	Herrero	o, M		
Fax: +49 89 2399 - 4465			Telephon	ne No. ±49.89 2399.8542		

International application No. PCT/US00/18051

1	th ar	With regard to the <b>elements</b> of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)): <b>Description, pages:</b>							
	1-	18	as originally filed						
	CI	aims, No.:							
	1-2	28	as originally filed						
2.	Wi lan	th regard to the <b>lang</b> guage in which the i	puage, all the elements marked above were available or furnished to this Authority in the international application was filed, unless otherwise indicated under this item.						
	Th	These elements were available or furnished to this Authority in the following language: , which is:							
		the language of a	translation furnished for the purposes of the international search (under Rule 23.1(b)).						
			blication of the international application (under Rule 48.3(b)).						
			ranslation furnished for the purposes of international preliminary examination (under Rule						
3.	Wit	h regard to any <b>nuc</b> ernational preliminar	leotide and/or amino acid sequence disclosed in the international application, the y examination was carried out on the basis of the sequence listing:						
		contained in the int	ernational application in written form.						
			he international application in computer readable form.						
			ently to this Authority in written form.						
			ently to this Authority in computer readable form.						
	The statement that the subsequently furnished written sequence listing does not go beyond the disclosure international application as filed has been furnished.								
		The statement that listing has been fur	the information recorded in computer readable form is identical to the written sequence nished.						
4.	The	amendments have	resulted in the cancellation of:						
		the description,	pages:						
		the claims,	Nos.:						
		the drawings,	sheets:						
5.		This report has bee considered to go be	n established as if (some of) the amendments had not been made, since they have been eyond the disclosure as filed (Rule 70.2(c)):						

International application No. PCT/US00/18051

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6.	Ad	ditional observations, if ı	necessa	ıry:	
	The	e questions whether the	claimed ly applic	l invention cable hav	d to novelty, inventive step and industrial applicability on appears to be novel, to involve an inventive step (to be nonve not been examined in respect of:
	×	claims Nos. 17-26 with	respec	t to indus	strial applicability.
be	cau	se:			
	Ø	the said international a does not require an inte see separate sheet	pplication ernation	on, or the al prelimi	e said claims Nos. 17-26 relate to the following subject matter which inary examination ( <i>specify</i> ):
		the description, claims that no meaningful opin	or draw nion cou	ings ( <i>indi</i> Id be forr	licate particular elements below) or said claims Nos. are so unclear med (specify):
		the claims, or said clain could be formed.	ns Nos.	are so ir	nadequately supported by the description that no meaningful opinior
		no international search	report h	as been	established for the said claims Nos
2.	2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:				ination cannot be carried out due to the failure of the nucleotide y with the standard provided for in Annex C of the Administrative
		the written form has not	been fu	urnished (	or does not comply with the standard.
		the computer readable	form has	s not bee	en furnished or does not comply with the standard.
V.	Rea cita	soned statement unde tions and explanations	r Article	e 35(2) w rting suc	vith regard to novelty, inventive step or industrial applicability;
1.	Stat	ement			
	Nov	elty (N)	Yes: No:	Claims Claims	1-28
	Inve	ntive step (IS)	Yes: No:	Claims Claims	1-28
	Indu	strial applicability (IA)	Yes:	Claims	1-16, 27, 28

International application No. PCT/US00/18051

No: Claims

2. Citations and explanations see separate sheet

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted: see separate sheet

# VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made: see separate sheet

# SECTION III

Claims 17-26 relate to medical uses considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

## **SECTION V**

- 2. CITATIONS AND EXPLANATIONS
- 2.1 The following document has been considered for the purposes of this report:
  - D1: Waclawek, M. et al (1998) Biology of Reproduction 59:1230-1239 (also cited in the application)
- 2.2 Inventive step (Art. 33(3) PCT)

The present application does not satisfy the criterion set forth in Art. 33(3) PCT because the subject-matter claimed does not involve an inventive step (Rule 65(1)(2) PCT)

No experimental support can be found elsewhere in the description as originally filed showing that the expected technical effects (i.e. immunocontraception or immunosterilization) are obtained.

The technical information provided in Examples I, II and III does not go beyond the teachings of D1. In this regard see that present page 14, lines 25-27 states that in order to isolate avian zona pellucida proteins for the purposes of the alleged invention (Example I) the procedure for isolating perivitelline membranes (pvm) from laid eggs reported in D1 can also be used. It is noted that in addition to the isolation of pvm and characterization of chZPC (chicken homologue of zona pellucida protein-3) D1 discloses the administration (three series of intradermal injections) of purified chZPC in combination with an adjuvant (Freund's complete

or incomplete adjuvant) to rabbits, whereby rabbit anti-chZPC antibodies were

animals (cf D1, page 1231, left column, 5th paragraph).

In spite of the fact that present Example III refers to "Immunosterilization of dogs using aZP vaccine" the information of relevance derivable from the experimental data therein provided is essentially the same as already known from D1, namely that avian ZP proteins are immunogenic in mammals (see above).

raised which could be recovered from the blood (immune sera) of the immunized

Moreover, although present Example IV refers to "Administration of mixed chicken/porcine ZP vaccine to Psitaccines" the experimental data therein provided do not substantiate that the expected technical results are obtained. First of all, in the light of the language employed (present tense, as in Example III) the possibility cannot be ruled out that Examples III and IV are merely of a predictive nature. Furthermore, with reference to the passage on page 17, lines 25-27, it is not evident that a reduction in egg production would provide a direct evidence of fertility impairment (at least of immunocontraception), since virgin hens are seemingly also capable of laying eggs (cf D1, page 1236, left column, lines 6-9).

Consequently, the application fails to contain the necessary technical information on the basis of which it could be possible to assess whether the various aspects of the invention as defined either in Claims 1-16 and 27-28 (fertility impairing vaccines) or Claims 17-26 (methods for impairing the fertility of an animal) involve an inventive step, contrary to the requirements of Art. 33(3) PCT.

#### SECTION VII

- The expression "hereby incorporated by reference" in respect of prior art 1. documents on page 17, lines 29-30 leads to a doubt as to whether the requirements of the description being self-contained are satisfied (see PCT Guidelines C-II, 4-17).
- The term "Tween" (pages 10, 15, 16 and 17) appears to be a registered trade 2. mark, but has not been acknowledged as such.

# **EXAMINATION REPORT - SEPARATE SHEET**

## SECTION VIII

- In the light of the supporting description on page 6, lines 30-31 it appears that, 1. instead of its present wording, Claim 12 was intended to read, e.g. "... wherein the polynucleotide is supplied as part of a vector! (Art. 6 PCT)
- 2. The statement in the description on page 17, lines 30-32 bridging over page 18 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).



# **PCT**

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 235.00310201  FOR FURTHER see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.								
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)						
PCT/HS 00/190E1	30/06/2000	01/07/1000						
PCT/US 00/ 18051 30/06/2000 01/07/1999								
Applicant								
THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC								
This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.								
i 1771	This International Search Report consists of a total of sheets.  X It is also accompanied by a copy of each prior art document cited in this report.							
Basis of the report								
	international search was carried out on the bas less otherwise indicated under this item.	sis of the international application in the						
the international search w Authority (Rule 23.1(b)).	as carried out on the basis of a translation of the	he international application furnished to this						
was carried out on the basis of the	e sequence listing:	nternational application, the international search						
. =	onal application in written form.	~						
	ernational application in computer readable form this Authority in written form.	n.						
	this Authority in computer readble form.							
the statement that the sub	osequently furnished written sequence listing do is filed has been furnished.	oes not go beyond the disclosure in the						
1 — "		s identical to the written sequence listing has been						
2. X Certain claims were fou	nd unsearchable (See Box I).							
3. Unity of invention is lac	king (see Box II).							
4. With regard to the <b>title</b> ,								
X the text is approved as su	bmitted by the applicant.							
the text has been establis	shed by this Authority to read as follows:							
5. With regard to the <b>abstract,</b>								
the text is approved as su								
	shed, according to Rule 38.2(b), by this Authoritie date of mailing of this international search rep							
6. The figure of the <b>drawings</b> to be published.	ished with the abstract is Figure No.							
as suggested by the appli	cant.	None of the figures.						
because the applicant fail	•							
because this figure better characterizes the invention.								

# **INTERNATIONAL SEARCH REPORT**

International application No. PCT/US 00/18051

B x I Obs rvations where certain claims wer f und unsearchable (Continuati n of it m 1 of first sh et)					
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:					
1. X Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:					
Although claims 17-26 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.					
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:					
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).					
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)					
This International Searching Authority found multiple inventions in this international application, as follows:					
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.					
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.					
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:					
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:					
Remark on Protest The additional search fees were accompanied by the applicant's protest.					
No protest accompanied the payment of additional search fees.					

# NATIONAL SEARCH REPORT

Information on patent family members

ternational Application No PCT/US 00/18051

cited in search report		date	I	member(s)	date
WO 9325231	Α	23-12-1993	AU	4303493 A	04-01-1994
			CA	2137363 A	23-12-1993
			US	5736141 A	07-04-1998

# IN NATIONAL SEARCH REPORT

ernational Application No PCT/US 00/18051

			701700 00, 10001					
A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K38/17 A61P15/18								
According to International Patent Classification (IPC) or to both national classification and IPC								
B. FIELDS	SEARCHED							
Minimum do IPC 7	Minimum documentation searched (classification system followed by classification symbols)  IPC 7 A61K							
	Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched							
1	lata base consulted during the international search (name of data b , CHEM ABS Data, WPI Data, EPO-Inte	•	search terms used)					
C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT							
Category °	Citation of document, with indication, where appropriate, of the re	elevant passages	Relevant to claim No.					
Х	M. WACLAWEK ET AL.: "The chicke homologue of zoan pellucida prot synthesiized by granuloma cells" BIOLOGY OF REPRODUCTION, vol. 59, 1998, pages 1230-1239, XP000978728		1-5,9-16					
Υ	cited in the application the whole document	6-8, 17-28						
X Furth	ner documents are listed in the continuation of box C.	χ Patent family m	embers are listed in annex.					
"A" docume conside "E" earlier of filing de "L" docume which i citation "O" docume other n	nt which may throw doubts on priority claim(s) or is cited to establish the publication date of another or other special reason (as specified) ent referring to an oral disclosure, use, exhibition or	shed after the international filing date not in conflict with the application but the principle or theory underlying the ar relevance; the claimed invention ed novel or cannot be considered to step when the document is taken alone ar relevance; the claimed invention ed to involve an inventive step when the ned with one or more other such docunation being obvious to a person skilled of the same patent family						
	actual completion of the international search		e international search report					
18	8 January 2001	06/02/20	01					
Name and m	nailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL - 2280 HV Rijswijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  Fax: (+31-70) 340-3016	Authorized officer Skelly,	J					

2



emational Application No.
PCT/US 00/18051

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT			
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
Y	P. WILLIS ET AL.: "Equine immunocontraception using porcine zona pellucida" J. EQUINE VET. SCI, vol. 14, no. 7, 1994, pages 365-370, XP000978916 cited in the application Disussion; page 366, column 1, paragraph 3	6-8, 17-28	
X	T. TSUDA ET AL.: "Isolation and characterisation of a chicken egg coat 97kd glycoprotein: the chicken hololog of zoan pellucida glycoprotein B" ZYGOTE, vol. 6, no. suppl1, 1998, pages s94-s95, XP000978733 the whole document	1-5	
A	M. BOER AT AL.: "Eine Übersicht über bisher in Zoologischen Gärten angewandte methoden der Kontrazeption" DER ZOOLOGISCHE GARTEN, vol. 66, no. 2, 1996, pages 93-105, XP000978732 page 94, paragraph 6 -page 95, paragraph 3	21,25-28	
A	WO 93 25231 A (DALHOUSIE UNIVERSITY) 23 December 1993 (1993-12-23) page 4, line 34 -page 5, line 12	25-28	

# **PATENT COOPERATION TREA**



From the INTERNATIONAL SEARCHING AUTHORITY

Mueting, Raasch, Gebhardt

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT

P.O. Box 581415 Minneapolis, MN 55458-1415 UNITED STATES OF AMERICA	OR THE DECLARATION  (PCT Rule 44.1)			
	Date of mailing (day/month/year) 06/02/2001			
Applicant's or agent's file reference 235.00310201	FOR FURTHER ACTION See paragraphs 1 and 4 below			
International application No. PCT/US 00/18051	International filing date (day/month/year) 30/06/2000			
Applicant				
THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC				
1. X  The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.  Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):  When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.  Where? Directly to the International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41–22) 740.14.35  For more detailed instructions, see the notes on the accompanying sheet.  2. The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.  3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:  the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.				
no decision has been made yet on the protest; the ap	plicant will be notified as soon as a decision is made.			
4. Further action(s): The applicant is reminded of the following:				
Shortly after <b>18 months</b> from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, before the completion of the technical preparations for international publication.				
Within 19 months from the priority date, a demand for international preliminary examination must be filed if the application wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even late				
Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.				

Name and mailing address of the International Searching Authori
European Patent Office, P.B. 5818 Patentlaan 2

Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Carla Louro

Authorized officer

FEB 12 2001

#### NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

## INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

## What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been fis filed, see below.

## How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application i English, the letter must be in English; if the language of the international application is French, the letter must be in French.

Notes to F rm PCT/ISA/220 (first sheet) (January 1994)

# NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

#### The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
  "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
  - "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- [Where various kinds of amendments are made]:
   "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

## "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

# It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

# Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

# Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

Notes to Form PCT/ISA/220 (second sheet) (January 1994)